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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,266	12/21/2000	Thomas Specht	SCH-1787	5221

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MARTINELL, JAMES

ART UNIT	PAPER NUMBER
1631	12

DATE MAILED: 11/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/674,266	SPECHT ET AL.	
	Examiner	Art Unit	
	James Martinell	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 February 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-22,25,28,29 and 33-38 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 23,24,26,27 and 30-32 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

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Claims 1-22, 25, 28, 29, and 33-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11. Applicants' sole argument in connection with the requirement for restriction is an assertion that the examiner has not established that an undue searching burden would be involved in examining the full scope of the claimed invention. This assertion is not convincing because claims 1-38 claim no fewer than 178 polynucleotides, 481 polypeptides, phage proteins that bind to no fewer than 481 polypeptides, and antibodies that bind to no fewer than 481 polypeptides. The searches for the broad categories of polypeptides, polynucleotides, and antibodies all diverge from one another and are not sufficiently coextensive to search without an undue burden being placed upon USPTO resources. Likewise, the searches of structurally dissimilar sequences must be performed separate from one another and the search of more than one such sequence in an application would place an undue burden on USPTO resources. Applicants elected SEQ ID NO: 181 for examination. Applicants did not address the issue independence and distinctness of the inventions. Claim 25 is withdrawn because it is drawn to polypeptides that bind SEQ ID NO: 181, not SEQ ID NO: 181 *per se*.

The disclosure is objected to because of the following informalities.

- (a) Each of the electronic Northern tables on pages 15-185 is improper in that the last two columns of the top sections of those tables run together (*i.e.* the last column is not aligned properly with the heading "T/N").
- (b) Pages 207-216 are in the German language.

Appropriate correction is required.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 23, 24, 26, 27, and 30-32 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The instant application does not disclose a patentable utility for polypeptides of SEQ ID NO: 181 or partial sequences contained within SEQ ID NO: 181. Table II at page 217 of the instant application reveals that SEQ ID NO: 181 is encoded by SEQ ID NO: 8. The results of the electronic Northern analysis on page 23 show a zero percent frequency of SEQ ID NO: 8 in both normal pancreas and in pancreas tumors. Thus, the disclosed and claimed (*i.e.*, claims 27, 28, and 30-31) utility of the use of polypeptides having SEQ ID NO: 181 or a partial sequence of SEQ ID NO: 181 is not specific, substantial, or credible.

Claims 23 and 24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 23 and 24 are so broadly written that they embrace polypeptides as they occur in nature.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 24, 26, 27, and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Table II at page 217 of the instant application reveals that SEQ ID NO: 181 is encoded by SEQ ID NO: 8. The results of the electronic Northern analysis on page 23 show a zero percent frequency of SEQ ID NO: 8 in both normal pancreas and in pancreas tumors. Thus, the instant application does not teach one of skill in the art how to use the claimed invention (*i.e.*, as a tool for finding active ingredients against pancreas tumors (claim 27), as a pharmaceutical agent in gene therapy (claim 30), for the production of pharmaceutical agents for the treatment of pancreas tumors (claim 31), or as a pharmaceutical agent (claim 32)). Additionally, the instant application makes no connection between any the results of an

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electronic Northern analysis and the level of, presence of, or absence of any biological molecule in any living system.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, 24, 26, 27, and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, incomplete, and incomprehensible.

- (a) Claims 23, 27, and 30-32 are vague and indefinite because they include non-elected SEQ ID NOs.
- (b) The recitation of "Polypeptide partial sequences" (claims 23, 24, and 26) is vague and indefinite because it is not clear whether applicants intend the claims to embrace partial sequences within SEQ ID NO: 181 or whether the claims are limited to SEQ ID NO: 181, which is itself a partial polypeptide sequence of some other, larger sequence.
- (c) The recitation of "according to sequences" (claim 23) is vague and indefinite because it is not known what is meant by the term.
- (d) The recitation of "these sequences" (claims 24 and 26) is vague and indefinite because the antecedent basis for the phrase is not clear.
- (e) The recitation of "polypeptide partial sequences" (claims 27, 30, and 31) is vague and indefinite because it is not clear whether applicants intend the claims to embrace partial sequences within SEQ ID NO: 181 or whether the claims are limited to SEQ ID NO: 181, which is itself a partial polypeptide sequence of some other, larger sequence.
- (f) Claims 27, 30, and 31 are incomplete because these method claims recite no positive process step.

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- (g) The recitation of "as tools" (claim 27) is vague and indefinite because the term is not defined nor is there any art recognized use of polypeptides as "tools."
- (h) The recitation of "the pancreas tumor" (claims 27, 30, and 31) is vague, indefinite, and incomplete because there is no antecedent basis for the term.
- (i) The recitation of "as pharmaceutical agents in gene therapy" (claim 30) is incomprehensible because it is not understood, nor does the instant application teach how to use a polypeptide for gene therapy.
- (j) The recitation of "polypeptide partial sequence" (claim 32) is vague and indefinite because it is not clear whether applicants intend the claims to embrace partial sequences within SEQ ID NO: 181 or whether the claims are limited to SEQ ID NO: 181, which is itself a partial polypeptide sequence of some other, larger sequence.
- (k) The recitation of "polypeptide partial sequence Seq. ID Nos." is vague and indefinite because it is not understood what is meant by the phrase.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 24, and 26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yu et al (WO 98/07749 (February 26, 98)). Figure 1 of Yu et al discloses a polypeptide that is 84.6% similar to SEQ ID NO: 181 of the instant application and that shares 175 contiguous amino acids with SEQ ID NO: 181 (see Figure 1 of the reference and the copy of the alignment attached to the reference). The polypeptide of Yu et al is embraced by the claims. In regard to claim 26, the recitation of "polypeptide partial sequence" renders the claim broad enough to embrace the polypeptide of Yu et al even though

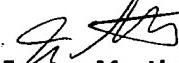
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the total sequence similarity is less than 90%. For example, the 175 amino acid polypeptide of Yu et al is 100% identical to the partial sequence of SEQ ID NO: 181, positions 32-206.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



**James Martinell, Ph.D.
Primary Examiner
Art Unit 1631**